IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

AMERICAN STOCK TRANSFER & TRUST COMPANY, LLC, as Trustee, Plaintiff, - against - SANOFI, Defendant.	Civil Action No.: 1:15-cv-08725 **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff American Stock Transfer & Trust Company, LLC, as Trustee ("AST" or the "Trustee") under the Contingent Value Rights Agreement between Sanofi and the Trustee, dated March 30, 2011, by its undersigned attorneys, as and for its Complaint against defendant Sanofi, alleges as follows:

NATURE OF THE ACTION

1. This is an action for breach of contract arising from Sanofi's failure to use Diligent Efforts (defined infra at ¶ 27) with respect to a drug called "Lemtrada" to achieve certain milestones that would have resulted in payments to the Trustee pursuant to the CVR Agreement, and for breach of the implied covenant of good faith and fair dealing arising from Sanofi's bad faith actions.

2. In February 2011, defendant Sanofi entered into a merger agreement (the "Merger Agreement") with Genzyme Corporation ("Genzyme"), a biotechnology corporation. Prior to and at the time of the Merger Agreement, Genzyme had been conducting clinical trials for a multiple sclerosis drug called Lemtrada.

3. In or before April 2011, Sanofi purchased more than 90% of Genzyme's shares to effectuate the merger. As part of the consideration for such shares, Sanofi issued contingent value rights (the "CVRs") to holders of Genzyme stock. For each share exchanged, the holder received $74 and one CVR.

4. These CVRs were subject to an agreement (the "CVR Agreement") between Sanofi and AST, as Trustee of an express trust for the benefit of the CVR holders (the "Holders"). A true and correct copy of the CVR Agreement is attached as Exhibit A. Pursuant to the CVR Agreement, Sanofi agreed to make up to approximately $3.8 billion in payments to former shareholders upon the completion of certain milestones relating to Lemtrada, including gaining Federal Drug Administration ("FDA") approval of Lemtrada on or before March 31, 2014, and obtaining specific sales volumes in defined periods.

5. In order to ensure that Sanofi would endeavor to meet those milestones, the parties agreed that Sanofi would meet a certain standard of conduct, defined in the CVR Agreement as "Diligent Efforts." Diligent Efforts requires that Sanofi ignore any cost of potential milestone payments in working to gain regulatory approval and commercialize Lemtrada, and that Sanofi act in a manner normally used by other companies in the pharmaceutical business to gain regulatory approval and commercialize Lemtrada, among other things. In contravention of this provision, Sanofi took those potential milestone payments into account in evaluating Lemtrada's profitability, embarked on a slow path to FDA approval and departed from its own drug commercialization patterns and those of others in the industry. As a result, Sanofi missed the contractual milestones and skirted its payment obligations of at least $708 million.

THE PARTIES

6. Plaintiff AST, the Trustee, is a limited liability trust company organized under the laws of the state of New York and located at 6201 15th Avenue in Brooklyn, New York. AST has as its sole member Armor Holding II LLC. The sole member of Armor Holding II LLC is Armor Holdco, Inc., a Delaware corporation.

7. The Trustee, as trustee of an express trust for the benefit of the Holders, brings this action pursuant to Section 4.1, Section 8.1, and Section 8.2 of the CVR Agreement.

8. Defendant Sanofi is incorporated under the laws of France as a *société anonyme*, a form of limited liability company, with its principal place of business in Paris, France. Sanofi is a global pharmaceutical company engaged in the research, development, manufacturing, and marketing of healthcare products. The CVR Agreement defines an Affiliate of Sanofi, in part, as "any other Person directly or indirectly controlling or controlled by or under direct or indirect common control with such specified Person." Genzyme, a wholly owned subsidiary of Sanofi, is an Affiliate of Sanofi.

JURISDICTION AND VENUE

9. This Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332 and the amount in controversy, without interest and costs, exceeds the sum or value specified therein.

10. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(2).

11. Pursuant to Section 1.10 of the CVR Agreement, Sanofi has agreed to submit to the exclusive jurisdiction and venue of the United States District Court for the Southern District of New York.

12. As specified under Section 8.1(b) of the CVR Agreement, the Trustee gave written notice to Sanofi by certified mail that Sanofi had breached the CVR Agreement and

requesting Sanofi to remedy the breaches identified therein (the "Notice of Breach"). Sanofi received the Notice of Breach on or before August 7, 2015. At least 90 days have passed since Sanofi was given the Notice of Breach, and the breaches identified therein have not been remedied.

THE ALLEGATIONS

13. Under the CVR Agreement, Sanofi agreed to make payments to the Trustee, as trustee of an express trust for the benefit of the Holders, upon the occurrence of certain milestones related to the regulatory approval and sales volume of Genzyme's multiple sclerosis drug Lemtrada. These milestones are described in the CVR Agreement as the Approval Milestone and the Product Sales Milestones.

14. Under the CVR Agreement, the parties agreed that Sanofi would use "Diligent Efforts" to achieve the Approval Milestone and the Product Sales Milestones. Diligent Efforts include causing Genzyme to take certain actions to enable the achievement of those milestones and require that Sanofi not take into account the payments to the Trustee, on behalf of the Holders, under the CVR Agreement when calculating profit.

15. Sanofi breached the CVR Agreement by, among other things, failing to use Diligent Efforts to achieve the Approval Milestone and the Product Sales Milestones, not one of which has been achieved. In particular,

a. Sanofi failed to cause Genzyme to follow the recommendations of the FDA and customary industry practice with respect to obtaining timely regulatory approval of Lemtrada and failed to cause Genzyme to submit an adequate application for FDA approval of Lemtrada that addressed the FDA's repeated concerns. As a result of its failure to use such efforts and employ such resources normally used by other companies in the

pharmaceutical business, Sanofi missed the Approval Milestone Deadline (as defined below) and limited Lemtrada's use in the United States to a third-line therapy, thereby harming the prospects of reaching the Product Sales Milestones.

b. Sanofi failed to devote adequate resources to the promotion and commercialization of Lemtrada, including by failing to cause Genzyme to promote and commercialize Lemtrada in a manner normally used by other companies in the pharmaceutical business in the promotion of such a product. This failure to use efforts and employ resources normally used in the pharmaceutical business relating to the promotion and commercialization of such a product has not only led Sanofi to miss Product Sales Milestone #1 (as defined below), but has harmed and continues to harm the prospects of reaching future Product Sales Milestones.

16. These failures to use Diligent Efforts constitute a breach of the CVR Agreement.

17. In addition to its failure to use Diligent Efforts, Sanofi engaged in bad faith conduct designed to keep Lemtrada sales below a contractual threshold and depress the trading price of the CVRs so as to maximize its opportunity to exercise its option to purchase the CVRs at a discount. In doing so, Sanofi has breached the implied covenant of good faith and fair dealing in the CVR Agreement.

18. Sanofi's actions and inaction deprive the Trustee, as trustee of an express trust, of its right to receive payments, on behalf of the Holders, under the CVR Agreement and have caused damages.

I. Sanofi's Issuance of Contingent Value Rights

19. Genzyme is a biotechnology company that specializes in the treatment of rare diseases and multiple sclerosis. Pursuant to the Merger Agreement, Genzyme became a wholly owned subsidiary of Sanofi.

20. At the time of the merger, Genzyme had spent years developing and testing a drug with an active ingredient called "alemtuzumab" for the treatment of patients with multiple sclerosis. Genzyme has referred to this drug as Lemtrada.

21. Sanofi's negotiations with Genzyme leading up to the merger involved disagreement over the value of Genzyme, particularly with respect to the business potential of Lemtrada. In explaining its rejection of Sanofi's initial offers, Genzyme argued that Lemtrada's business potential was not accurately reflected in its stock price and that Sanofi's offers based solely on the stock price undervalued Genzyme.

22. In an effort to resolve the disagreement over the value of Genzyme and Lemtrada's impact on that value, Sanofi agreed that for each Genzyme share it purchased, it would pay $74 and issue a CVR to each holder of a Genzyme share. These CVRs, which are subject to the CVR Agreement, entitled the Trustee, as trustee of an express trust, to receive certain payments for the benefit of the Holders, when the regulatory approval and sales volume of Lemtrada reached certain benchmarks. The CVRs were issued with the understanding that Sanofi would make the required Diligent Efforts to obtain such approval and sales volume by those deadlines. In Genzyme's Schedule 14D-9, filed with the Securities and Exchange

Commission on March 7, 2011, Genzyme estimated the value of a CVR at $5.58, as of March 2011, and recommended that its shareholders approve the merger.

II. Operation of the CVR Agreement

A. Sanofi's Obligations Under the Approval and Product Sales Milestones

23. The CVR Agreement provides that Sanofi must make certain payments to the Trustee upon the occurrence of certain events regarding Lemtrada.

a. *Approval Milestone*: Holders are entitled to receive $1 per CVR (the "Approval Milestone Payment") within twenty business days following the date that Sanofi or one of its Affiliates receives FDA approval of Lemtrada for treatment of multiple sclerosis, if such date is on or before March 31, 2014 (the "Approval Milestone Deadline," and achievement of such approval by such Approval Milestone Deadline being the "Approval Milestone").

b. *Product Sales Milestone #1*: Holders are entitled to receive $2 per CVR within a defined period of time following the first instance where the sum of (i) the aggregate Lemtrada sales for certain qualifying major markets plus (ii) the aggregate Lemtrada sales achieved in all countries that are not qualifying major markets exceeds $400 million, during certain periods ("Product Sales Milestone #1"). Based on the date of the first commercial sale of Lemtrada, by operation of the CVR Agreement, no Lemtrada sales occurring after December 31, 2016 will be counted towards the achievement of Product Sales Milestone #1.

c. *Product Sales Milestone #2*: Holders are entitled to receive $3 per CVR within a defined period of time after the global sales of Lemtrada are equal to or in excess of $1.8 billion during any four consecutive quarters ("Product Sales Milestone #2").

d. *Product Sales Milestone #3*: Holders are entitled to receive $4 per CVR within a defined period of time after the global sales of Lemtrada are equal to or in excess of $2.3 billion during any four consecutive quarters (exclusive of any quarters used for achievement of previous milestones) ("Product Sales Milestone #3").

e. *Product Sales Milestone #4*: Holders are entitled to receive $3 per CVR within a defined period of time after the global sales of Lemtrada are equal to or in excess of $2.8 billion during any four consecutive quarters (exclusive of any quarters used for achievement of previous milestones) ("Product Sales Milestone #4," and, together with Product Sales Milestone #1, Product Sales Milestone #2, and Product Sales Milestone #3, the "Product Sales Milestones," and together with the Approval Milestone, the "Milestones").

24. The CVR Agreement further provides that if Product Sales Milestone #2 is achieved but the Approval Milestone is not achieved, Sanofi must pay an additional $1 per CVR for Product Milestone #2.

25. As outlined further below, Sanofi has not achieved any of the Milestones, including the Approval Milestone, the deadline for which passed on March 31, 2014. On October 29, 2015, Sanofi disclosed that, based on actual sales trends to date, Sanofi does not

expect that Product Sales Milestone #1 will be met. The Trustee has received no payments in connection with the Milestones.

B. Sanofi's Obligations to Use Diligent Efforts Under the CVR Agreement

26. Pursuant to Section 7.10 of the CVR Agreement, Sanofi is obligated to "use Diligent Efforts to achieve the Approval Milestone and the Product Sales Milestones."

27. "Diligent Efforts," as defined in the CVR Agreement, means:

> with respect to the Product, efforts of a Person to carry out its obligations, and to cause its Affiliates and licensees to carry out their respective obligations, using such efforts and employing such resources normally used by Persons in the pharmaceutical business relating to the research, development or commercialization of a product, that is of similar market potential at a similar stage in its development or product life, taking into account issues of market exclusivity, product profile, including efficacy, safety, tolerability and convenience, the competitiveness of alternate products in the marketplace or under development, the availability of existing forms or dosages of alemtuzumab for other indications, the launch or sales of a biosimilar product, the regulatory environment and the profitability of the applicable product (including pricing and reimbursement status achieved) consistent with the Company's publicly reported financial statements (assuming the Company will not treat payments to [Bayer] as an expense for purposes of this clause, or the achievement of Milestones in such a manner, that would reduce the profitability of the Product) and other relevant factors, including technical, commercial, legal, scientific and/or medical factors. "Diligent Efforts" shall include, but shall not be limited to, the following: (a) making expenditures in relation to the Product that are consistent with expenditures normally made by Persons in the pharmaceutical business in connection with products of similar market potential at similar stages in their development or product life; (b) implementing and maintaining appropriate Product and patient support services (including, but not limited to, risk identification and minimization programs and reimbursement support services); (c) initiating and completing all post-marketing approval commitments; (d) promptly seeking pricing approvals and/or minimally restrictive payer coverage decisions in the Major Markets; (e) fulfilling obligations under any copromotion agreement or arrangement with [Bayer] should [Bayer] exercise its right to co-promote the Product; (f) setting or seeking a commercial price for the Product that is consistent with the profile of the Product, including seeking premium pricing based on the effectiveness of the Product; (g) promoting the Product for all labeled multiple sclerosis indications; and (h) otherwise

> fulfilling the obligations of the Company and its Affiliates under Existing Licenses, including fulfilling obligations pursuant to the LAPA in order to maintain the rights to develop and commercialize the Product granted thereunder.

28. Sanofi's obligations to take certain actions to achieve the Milestones included the obligation to cause its Affiliate, Genzyme, to take certain actions so that the Milestones would be met.

C. Sanofi's Obligations to Bayer Under the CVR Agreement

29. As part of the merger with Genzyme, Sanofi also assumed Genzyme's obligations under a prior License and Asset Purchase Agreement, dated as of March 30, 2009 (the "LAPA"), with Bayer Schering Pharma AG ("Bayer"). That agreement gave Genzyme worldwide development and marketing rights to Lemtrada, as well as the rights to another drug called "Campath," which used the same active ingredient, alemtuzumab, but was specifically developed for the treatment of chronic lymphocytic leukemia.

30. The LAPA provides that in exchange for Bayer's funding of a portion of the costs to develop Lemtrada, Bayer is to receive, among other things, a percentage of sales of Lemtrada and Campath up to a maximum amount or over the course of a maximum number of years. Bayer is also entitled to certain milestone payments based on the annual sales of both Campath (between 2011 through 2013) and Lemtrada (after 2012). Under the agreement, Bayer also has the option of co-promoting Lemtrada with Genzyme.

31. As of December 31, 2014, Sanofi listed the fair value of this contingent liability to Bayer at €896 million.

D. Sanofi's Failure Purchase Option Under the CVR Agreement

32. The CVR Agreement provides Sanofi with a "Failure Purchase" option to purchase and cancel all (but not less than all) of the outstanding CVRs upon the occurrence of a

"CVR Failure Event." Sanofi can exercise the Failure Purchase option any time after April 1, 2017, if two conditions are met:

a. the volume-weighted average price paid per CVR for all CVRs traded over the forty-five (45) trading days prior to such date is less than fifty cents ($0.50) (the "Failure Purchase Price"); and

b. "Product Sales" (as defined in the CVR Agreement) in the four (4) calendar quarters ended immediately prior to such date are less than one billion dollars ($1,000,000,000.00) in the aggregate.

33. If Sanofi exercises the Failure Purchase option, Sanofi must then purchase all of the outstanding CVRs for the Failure Purchase Price. Sanofi must then cancel all of the CVRs, such that "all right, title and interest in and to the Securities and any CVR Payment or any amounts due under this CVR Agreement, if any, . . . ceases to accrue."

III. Sanofi Failed to Use Diligent Efforts to Achieve the Approval Milestone

A. Sanofi and Genzyme's Inadequate Application for Lemtrada

34. To obtain a license to introduce a biological product,[1] such as Lemtrada, for a new particular use into interstate commerce in the United States, an entity must submit a biologics license application ("BLA") to the FDA. If the FDA has already approved a biosimilar product[2] for a different use, then the entity seeking approval must submit a supplemental biologics license application ("sBLA"). A BLA and sBLA must present specific information, data, and analyses related to the drug. *See* 21 C.F.R. § 601.20.

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[1] A "biological product" or "biologic" is a product made from natural resources, such as sugars, proteins, nucleic acids, or a combination of these substances, that replicates natural substances such as enzymes, antibodies, or hormones. Among other uses, biologics can be used to treat, prevent, or diagnose disease.

[2] A "biosimilar" product is a type of biological product that is highly similar to an already FDA-approved biological product (called the "reference product"), and is shown to have no clinically meaningful difference from the reference product.

35. To obtain FDA approval for a license, a BLA must, among other things, present substantial evidence of a drug's efficacy by demonstrating that the clinical trials were "adequate and well-controlled." *See* 21 C.F.R. § 314.126.

36. In 2001, the FDA issued a license for the introduction into interstate commerce of alemtuzumab, marketed as Campath, for the treatment of chronic lymphocytic leukemia.

37. After this approval, Genzyme also pursued the development of a biosimilar form of alemtuzumab for the treatment of multiple sclerosis. Over the course of the next seven years, the FDA and Genzyme were in communication concerning Genzyme's Phase II and Phase III clinical trials studying alemtuzumab for the treatment of multiple sclerosis, under the trade name Lemtrada. During this time, the FDA communicated to Genzyme that it had significant concerns regarding the clinical trial design.

38. Genzyme was aware, through repeated communications from the FDA, that the FDA disfavored its Lemtrada Phase III clinical trial design because the trial was not a "double-blind" trial. A "double-blind" study is a study in which neither the subjects nor the researchers know which treatment—either the drug under study or a comparator drug or placebo—a subject receives.

39. Instead of a double-blind design, Genzyme used an "open-label, rater-blind" design in the Lemtrada clinical trials. An "open-label" study is a study in which both the subjects and the researchers know which treatment a subject receives. An "open-label, rater-blind" study is a form of an open-label study where, even though both the subject and researcher know which treatment was received, certain conditions reported by the subject are analyzed by a "rater" who is not provided with information identifying which treatment the subject received.

40. Subsequent to its acquisition by Sanofi, on or before June 12, 2012, Genzyme submitted an inadequate sBLA (as subsequently amended, the "Application") to the FDA, purportedly seeking approval of Lemtrada for the treatment of relapsing multiple sclerosis. Sanofi caused Genzyme to submit the inadequate Application.

41. In August 2012, Sanofi and Genzyme announced that the FDA had not accepted the Application for filing and had issued a "Refuse to File" letter in response to the Application. In the "Refuse to File" letter, the FDA made specific recommendations and requests to Sanofi and Genzyme regarding the Application, and requested that Sanofi and Genzyme modify the presentation of the data in further submissions relating to the Application to enable the agency to better understand and evaluate the data within the Application. Sanofi and Genzyme's inadequate Application and the FDA's ensuing "Refuse to File" letter delayed FDA approval.

42. Three months later, in November 2012, Sanofi and Genzyme submitted a revised Application, which the FDA accepted for review in January 2013.

43. In December 2013, the FDA denied approval of Lemtrada, taking the position that Genzyme had not submitted sufficient evidence from adequate and well-controlled studies that demonstrated that the benefits of Lemtrada outweighed its adverse effects. Sanofi and Genzyme announced that Genzyme planned to appeal the FDA decision, and that Sanofi did not anticipate that the Approval Milestone would be met.

44. However, on April 7, 2014, only one week after the Approval Milestone Deadline had passed, Sanofi and Genzyme announced in a Press Release that they no longer expected to pursue an appeal, but would resubmit the sBLA, with additional information to

"specifically address issues previously noted by the FDA in its December 27, 2013 Complete Response Letter."

45. In April 2014, approximately two weeks after the Approval Milestone Deadline had passed, Sanofi and Genzyme submitted an amendment to the Application. Between April 2014 and November 2014, at the FDA's request, Sanofi and Genzyme made at least thirty-two submissions to the FDA in connection with the Application, supplying information that could have and should have been supplied in an earlier time period that would have allowed Sanofi to meet the Approval Milestone Deadline.

46. The FDA approved Lemtrada in November 2014, approximately seven months after the Approval Milestone Deadline. This approval was based on the same or substantially the same clinical trial data available to Sanofi and Genzyme at the time of the previous sBLA submissions.

47. Manufacturers of pharmaceutical products, including Sanofi, understand that the longer a product spends pending FDA approval, the less time the manufacturer will have to sell such product to the public prior to patent expiration. The FDA's standard time period for issuing a decision on an application for a license to sell a new drug is within ten months of the submission of the application.

48. The FDA also sells "Priority Review Vouchers" that grant applicants an expedited six-month review of applications for FDA approval of pharmaceutical products rather than the ten-month standard review. Sanofi recognized the value in obtaining expedited FDA approval of other of its products when, in mid-2015, Sanofi purchased a Priority Review Voucher for $245 million. Extrapolating from this $245 million purchase price, Sanofi valued the right to buy an accelerated FDA review at over $60 million per month.

49. Among the ten multiple sclerosis drugs with the highest sales in 2013, FDA approval was granted an average of thirteen months after the application was filed. In contrast, because of Sanofi and Genzyme's failure to use the required efforts in submitting the Application, Lemtrada was approved 29 months after Genzyme and Sanofi submitted the initial application in June 2012.

B. Sanofi and Genzyme Failed to Address Known Concerns Expressed by the FDA

50. Sanofi failed to use such efforts and employ the resources normally used by companies in the pharmaceutical business to present and explain the design, execution, and results of the Lemtrada trials in the Application to the FDA such that the Application would be approved by the Approval Milestone Deadline.

51. Sanofi failed to use the efforts and employ the resources normally used by a company in the pharmaceutical business by not causing Genzyme to submit an adequate Application to the FDA in November 2012, and by causing Genzyme to delay, impede, and otherwise frustrate the FDA's review of the Application.

52. As discussed *supra*, Genzyme used an open-label, rater-blind design in the Lemtrada clinical trials, which was disfavored by the FDA. The use of an open-label, rater-blind design meant that, in the Lemtrada clinical trials, patients and treating physicians knew whether the patients received Lemtrada or the comparison drug REBIF (interferon beta-1a) ("Rebif").

53. To achieve FDA approval based on an open-label, rater-blind trial, Sanofi and Genzyme would have had to adequately address and alleviate the FDA's known concerns about this type of trial. In the Application, Sanofi and Genzyme failed to do so.

54. Despite constructive feedback provided by the FDA throughout the development of Lemtrada and during the Application process, the Application did not address

the FDA's concerns about the shortcomings of the Phase III clinical trials, such as the trial design's susceptibility to bias and its influence on clinical outcomes.

55. On November 8, 2013, the FDA released briefing materials ("Briefing Materials") in advance of the November 13, 2013 FDA Peripheral and Central Nervous System Drugs Advisory Committee (the "Advisory Committee") meeting.

56. The Briefing Materials documented that, from 2006 through 2011, the FDA advised Sanofi and Genzyme of numerous concerns it had with Genzyme's clinical trials for Lemtrada. Such materials also described the FDA's findings that the Application failed to address the FDA's previously communicated concerns regarding the conduct of the Lemtrada trials.

57. The concerns raised in the Briefing Materials were discussed at the November 13, 2013 Advisory Committee meeting. Significant concerns were raised regarding, among other things, Sanofi and Genzyme's failure to adequately address the effect of bias as a result of the open-label, rater-blind studies. Specifically, the FDA was concerned that there was:

- Insufficient evidence presented that Genzyme took adequate steps to control for bias in the Lemtrada trials; and
- Inadequate evidence presented to show that the bias controls employed were adequate such that the data reliably demonstrated the efficacy of Lemtrada regarding the two main clinical outcomes of (i) rate of disability progression (referred to as "sustained accumulation of disability" or "SAD") and (ii) relapse rate.

1. Sanofi and Genzyme Failed to Address the FDA's Concerns in the Application

58. In the Application, Sanofi and Genzyme ignored the FDA's repeated, expressed concerns about bias in the clinical trials, and the FDA's requests for specific information that would have assisted the FDA in resolving its concerns without undue delay.

59. For example, on November 13, 2013 at the Advisory Committee meeting, Dr. Billy Dunn of the FDA stated that "we [the FDA] gave [Sanofi and Genzyme] very specific information that had to do with what types of information they could include in order to help increase a demonstration of the rigor of the trial, help us in our analysis of assessing the effects of potential bias in the trial." Transcript of the November 13, 2013 Advisory Committee Meeting, excerpts attached as Exhibit B ("Advisory Committee Tr.") at 268:12-20. This information was not included in the Application.

60. The FDA had specifically "reiterated the concerns about the lack of blinding, and requested that the applicant submit a full discussion and analysis of the impact of having the patients and treating physicians unblinded." Advisory Committee Tr. at 136:16-137:5. Sanofi and Genzyme did not "directly address[] the impact of unblinding the patients and the treating physicians" in the Application. *Id.*

61. Sanofi and Genzyme also failed to address the uneven dropout rates in the Phase III trials in the Application. In one of the Phase III studies, the dropout rate, which is the percentage of patients who dropped out of the clinical trial before receiving any treatment, was 12.6 percent for the Rebif group, as compared with 2.3 and 1.7 percent in the two Lemtrada groups that were included in the study. Because patients were unblinded before treatment and aware of the study trial group in which they had been placed, *i.e.*, they knew whether they would be receiving the new drug under study (Lemtrada), or the older, known drug (Rebif), the uneven dropout rate is evidence that knowledge of the treatment group may have influenced patient behavior. That is, the patients who knew they would be receiving the drug under study may have felt more positive about the results of the treatment while patients receiving Rebif, a drug already available, may have felt less positive about the treatment results. This disparity in the dropout

rates for the Lemtrada group and the Rebif group caused the FDA "great concern" that the data did not represent a randomized population. Advisory Committee Tr. at 164:15-165:22.

62. The Application also failed to address the FDA's concerns regarding taking baseline assessments *after* patients had been informed of their treatment group. A baseline assessment is an evaluation of the status of the disability in a patient prior to treatment in a clinical trial. The patients' knowledge of their treatment assignments prior to treatment created concerns that their baseline assessment was compromised, such that this assessment was biased or potentially invalid. Advisory Committee Tr. at 164:15-165:22.

63. Further, the Application *failed* to adequately explain whether any bias from unblinding patients was adequately controlled by rater-blinding. Although the rater does not know which treatment a patient received, the raters score the disability status or neurological impairment of each patient ("EDSS" scores)[3] to measure the effect of treatment on a patient's disability. These EDSS scores were based on subjective information provided by the unblinded participants. Advisory Committee Tr. at 140:3-142:9.

64. The Application failed to address how these issues might affect the robustness of the data and the conclusions that could be drawn from the clinical outcomes. For example, Dr. Marler of the Advisory Committee expressed the following concerns:

> [W]e asked the question were adequate measures taken to minimize bias on the part of the subjects, observers, and analysts of the data. It is in the control of bias that the [Phase III Lemtrada] trials have their most serious weaknesses. . . . First, the primary SAD [sustained accumulation of disability] and relapse events are highly dependent on subjective responses from patients and treating physicians. Second, the applicant's methods for controlling bias inherent in reports from unblinded patients and treating physicians are inadequate[.]

[3] "EDSS" is the Kurtzke Expanded Disability Status Scale, a widely used, standard assessment that measures the disability status or neurological impairment of patients with multiple sclerosis.

> Most of these exam items depend directly on the effort exerted by the subject to perform a test, describe a feeling, or recall a symptom. This is what I mean when I say subjective. [sic] Conclusion. Although there are hundreds of items recorded, the EDSS is very subjective, relying heavily on the patient's subjective observations.
>
> The bias that the trial protocols permit in the underlying EDSS scores by unblinding the patients, and to some extent the treating physician, is carried forward into the determination of disability events. Hence, blinding EDSS raters does not control bias introduced by patients and treating physicians in the determination of the SAD outcome because the EDSS scores are themselves biased.

Advisory Committee Tr. at 140:3-142:9.

65. Additionally, the Application failed to adequately address the effect of bias based on the subjective nature of the patient examination and the patient's knowledge of the treatment being received in the findings on the efficacy of Lemtrada on relapse rates. Dr. Marler expressed the following concern:

> The main point here is that all the data that the Relapse Adjudication Panel looks at originated from an unblinded source, the patient primarily and the treating physician secondarily. . . . The Relapse Adjudication Panel had no untainted source of information and, hence, could not distinguish the effects of alemtuzumab or interferon from those of bias, placebo effects, and baseline differences in the study population. . . . So the conclusion about this second characteristic is that the [Phase III Lemtrada] trials did not adequately control bias on the part of the subjects and the treating physicians.

Advisory Committee Tr. at 146:6-147:8.

66. The Briefing Materials included the following statement summarizing Sanofi and Genzyme's failure to present an adequate Application:

> In general, the application did not convey objectivity and did not explore alternative explanations for the results that were reported. The submission did not explain unusual features of the trial such as the determination of baseline EDSS scores after randomization in many subjects. The discussion of the blinding was incomplete and did not adequately address FDA concerns about the extent of bias introduced by unblinded subjects and treating physicians or estimate the possible effects of unblinding

patients and treating physicians on the interpretation of the results. Briefing Materials at 20 (excerpts attached hereto as Exhibit C).

2. Sanofi and Genzyme's Expressed Rationales to the FDA for Not Conducting Double-Blind Clinical Trials Were Inadequate

67. Sanofi and Genzyme also did not present to the FDA adequate rationales as to why they did not conduct a double-blind study. During the November 13, 2013 meeting, Sanofi and Genzyme representatives stated that among the rationales for not pursuing a double-blind study were that, even if a double-blind study had been pursued, (i) the use of Rebif as a comparison drug and (ii) the known side effects of Lemtrada (namely, a significant rash on most patients) would have effectively unblinded the study participants. *See* Advisory Committee Tr. at 121:15-124:18.

68. Sanofi and Genzyme's stated rationales to the FDA for not conducting a double-blind study were inadequate.

69. Sanofi and Genzyme's first rationale—the use of the comparison drug, Rebif—was inadequate, in part, because other pharmaceutical companies have conducted double-blind clinical trials for drugs similar to Lemtrada, using the same comparison drug.

70. For example, F. Hoffman La Roche Ltd. ("Roche") conducted two double-blind, double-dummy[4] Phase III clinical trials (hereinafter, the "Roche Double-Blind MS Studies") to evaluate the efficacy and safety of a drug called "ocrelizumab" which, like Lemtrada, is a treatment for people with relapsing multiple sclerosis.

[4] A "double-blind, double-dummy" study is a type of double-blind study in which all subjects are given both a placebo and an active drug in alternating study periods. Neither the subjects nor the researchers know which treatments the subject receives. This type of study is used when studying two treatments that cannot be made identical, such as when comparing a drug administered by intravenous infusion (such as Lemtrada) to a drug administered by injection (such as Rebif). In that example, the patient groups in a double-dummy study may receive the following: Group 1 (active intravenous infusion, placebo injection), Group 2 (placebo intravenous infusion, active injection), Group 3 (placebo intravenous infusion, placebo injection).

71. In the Roche Double-Blind MS Studies, ocrelizumab was compared against administration of Rebif, the same drug that Genzyme used as a comparison in its rater-blinded studies. Unlike Lemtrada and ocrelizumab, which are both administered by intravenous infusion, Rebif is administered by subcutaneous injection three times per week.

72. The Roche Double-Blind MS Studies had other similarities with Genzyme's Phase III clinical trials for Lemtrada. Both Lemtrada and ocrelizumab are biological drugs for the treatment of patients with multiple sclerosis, and both trials primarily compared the effects of either the drug under study or Rebif on the two clinical outcomes of (i) rate of disability progression and (ii) relapse rate over a two-year period in patients that were administered either the drug under study or Rebif.

73. Thus, by virtue of the fact that Roche was able to conduct a double-blind, double-dummy study with Rebif, the same comparison drug, Sanofi and Genzyme's expressed rationale that use of Rebif would have effectively unblinded the study participants was inadequate to justify conducting an open-label study rather than a double-blind study.

74. Sanofi and Genzyme's second expressed rationale for not using a double-blind trial—that patients and researchers would have become unblinded based on Lemtrada's infusion-related side effects—was similarly inadequate because patients that received the comparison drug, Rebif, also experienced infusion-related side effects associated with the infusion of the steroid methylprednisolone, a part of treatment with Rebif. *See* Advisory Committee Tr. at 327:21-328:7 (FDA noting that those patients also had "a fairly high rate of [side-effect] events at the time of infusion even though they knew that they were not alemtuzumab"). As the FDA itself noted, the fact that patients receiving Rebif also experienced

infusion-related side effects "is actually the best argument ***for*** a double-dummy study." *Id.* (emphasis added).

75. Thus, Sanofi and Genzyme's second stated rationale for not using a double-blind study, that of the known side effects of Lemtrada, was also inadequate to justify their use of a rater-blind study.

C. Sanofi's Failure to Use Diligent Efforts Resulted in the FDA's Denial of the Application and the Failure to Meet the Approval Milestone

76. Sanofi and Genzyme's failure to adequately present to the FDA the evidence obtained from the clinical trials, coupled with insufficient rationales for their trial design, caused the FDA to deny approval of Lemtrada prior to the Approval Milestone Deadline.

77. In denying the Application, the FDA issued a Complete Response Letter on December 27, 2013, explaining that it had determined that Sanofi and Genzyme did not provide evidence from adequate and well-controlled studies to support the effectiveness of Lemtrada for treating multiple sclerosis.

78. Although the Approval Milestone Deadline was March 31, 2014, Sanofi and Genzyme delayed submitting pertinent information to the FDA until after that deadline had passed and for almost four months from the denial of the Application. Between April and November 2014, Sanofi and Genzyme made at least thirty-two additional submissions relating to the Application. Sanofi and Genzyme made one or more submissions to the FDA relating to the Application on each of the following dates: April 15, 2014, May 15, 2014, May 20, 2014, June 13, 2014, July 1, 2014, July 2, 2014, July 10, 2014, July 15, 2014, July 18, 2014, July 21, 2014, July 22, 2014, July 23, 2014, July 29, 2014, July 30, 2014, August 4, 2014, August 6, 2014, August 7, 2014, August 8, 2014, August 27, 2014, September 5, 2014, September 8, 2014,

September 12, 2014, October 15, 2014, October 21, 2014, October 27, 2014, November 7, 2014, November 12, 2014, November 13, 2014, and November 14, 2014.

79. These thirty-two submissions were based on the data from the ***same clinical trials*** that were discussed in previous submissions related to the Application. The FDA approved the Application on November 14, 2014.

80. Sanofi's delay in achieving FDA approval adversely affected sales of Lemtrada all over the globe. As Sanofi's CEO, Christopher Viehbacher, stated in an investor call on October 28, 2014, "if the FDA does not approve a product straight away, even if you get it approved elsewhere, there is still a 'waiting to see what the FDA does'." Sanofi's failure to use Diligent Efforts to achieve the Approval Sales Milestone has led Sanofi to miss the Product Sales Milestone #1, and continues to adversely affect Sanofi's ability to meet each of the other Product Sales Milestones.

D. Sanofi's Failure to Use Diligent Efforts Resulted in the FDA Limiting Lemtrada to a Third-Line Therapy

81. In the Application, Sanofi and Genzyme failed to address the FDA's long-standing safety concerns associated with the use of Lemtrada. The safety data from the clinical trials for Lemtrada revealed that use of Lemtrada is associated with increased risk for malignancies such as thyroid cancer and melanoma, infusion reactions, infections, and autoimmune diseases such as thyroid disorders, immune thrombocytopenia and hemophilia. For example, more than eighteen (18%) percent of patients receiving Lemtrada in the clinical trials reported a thyroid adverse event over a three-year period compared with five percent (5%) of patients receiving Rebif in the clinical trials over the same time period. Genzyme was aware of these safety issues as early September 2005 when the FDA placed a clinical hold on the Lemtrada Phase II studies after the occurrence of three cases of severe immune

thrombocytopenia in patients receiving Lemtrada while none of the patients receiving Rebif in the clinical trials had confirmed immune thrombocytopenia. *See* Briefing Materials at 15-16.

82. Given the known safety profile for Lemtrada, Sanofi should have conducted and sponsored additional trials to determine how to manage and mitigate the side effects of Lemtrada, but it undertook no such effort. At the November 13, 2013 Advisory Committee meeting, Dr. Nyedra Booker of the FDA stated that "there is no specific strategies that have been identified [by Sanofi and Genzyme] that will prevent or lessen the frequency of the serious adverse events" based on the use of Lemtrada. Advisory Committee Tr. at 199:21-200:1.

83. Because of Sanofi and Genzyme's failure to use the required efforts to manage or mitigate these side effects, and to explain the management or mitigation of these side effects in the Application, the FDA approval required the marketing of Lemtrada as a "third-line" therapy, generally reserved for patients who have had an inadequate response to two or more drugs for the treatment of multiple sclerosis.

84. Because of the known safety profile for Lemtrada, the FDA also required that Sanofi and Genzyme put a Risk Evaluation and Mitigation Strategy ("REMS") program in place prior to approval of the Application. A REMS program is intended to ensure that the benefits of a drug or biologic outweigh its risks.[5] Sanofi and Genzyme should have developed a REMS program for Lemtrada that ensured adequate screening and monitoring for managing side effects in patients and more detailed follow-up and reporting of adverse events in treated

[5] A REMS program includes specific safety procedures required of healthcare professionals and distributors prior to prescribing, shipping, or dispensing a drug. These procedures may include specialized drug labeling, patient education through a medication guide or patient package insert, the requirement that healthcare professionals be certified to administer or dispense a drug, and additional monitoring or testing of a patient prior to or during administration of a drug.

patients. If Sanofi and Genzyme had used the efforts and employed the resources normally used by pharmaceutical companies, they would have developed a REMS program that would have resulted in Lemtrada's approval as a first-line or second-line therapy.

85. Sanofi and Genzyme's failure to conduct additional trials to manage and mitigate the known side effects of Lemtrada and to develop an appropriate REMS program led to the FDA limiting Lemtrada's use to a third-line therapy, thereby harming the prospects of reaching the Product Sales Milestones.

IV. Sanofi Did Not Use the Required Efforts to Commercialize and Promote Lemtrada

86. Sanofi also failed to use Diligent Efforts, including failing to cause Genzyme to take certain actions, to achieve the Product Sales Milestones.

87. Sanofi did not use the efforts or employ the resources normally used by companies in the pharmaceutical business to commercialize and promote Lemtrada, which resulted in depressed sales because Lemtrada was introduced into a healthcare professional and consumer market that was unfamiliar with Lemtrada.

88. For example, Sanofi did not use the efforts or employ the resources or make the expenditures normally used by companies in the pharmaceutical business to provide patients with support and information about Lemtrada or to inform doctors about Lemtrada. Among other things, Sanofi:

- Failed to timely commence a marketing campaign commensurate with the marketing campaigns of other companies in the pharmaceutical business after regulatory approval of Lemtrada. Indeed, in December 2014, a healthcare marketing business publication called Medical Marketing & Media reported that Sanofi was keeping Lemtrada consumer marketing materials from rolling out until at least six months after approval.

- Failed to put the Lemtrada sales force fully into place until February 2015, at least two months after the first commercial sale in the United States, and 15 months after the first worldwide commercial sale in Germany. Had Sanofi acted earlier, sales would have been substantially increased. In the first full quarter after the hiring of the sales force, sales for Lemtrada nearly doubled in the United States. In the first quarter where consumer marketing materials were made available, sales increased in the United States by another 30%.

- Failed to provide sufficient information to neurologists and provide sufficient physician and other relevant training for Lemtrada.

- Failed to locate and develop an adequate amount of infusion centers, especially in highly populated areas, to ensure patient access to Lemtrada treatment.

- Failed to meaningfully operate patient resources campaigns for Lemtrada.

89. These failures assured that sales would be depressed during the measuring period for the Product Sales Milestone #1, especially in the United States market, where, as Bill Sibold, senior vice president of Genzyme, acknowledged, "[a]bout 60 percent of the global market for multiple sclerosis is[.]" Had Sanofi taken actions normally used by companies in the pharmaceutical business to commercialize Lemtrada, including but not limited to, promoting Lemtrada, hiring and building out a sales force, providing sufficient information to physicians along with other relevant training, and making appropriate expenditures relating to the foregoing, sales during this period would have been significantly greater such that Sanofi would have achieved Product Sales Milestone #1 as early as the second quarter of 2015, but no later than the third quarter of 2015.

90. Instead, Product Sales Milestone #1 has not been met. On October 29, 2015, Sanofi announced that "[b]ased upon actual sales trends to date, Sanofi does not expect that the Product Sales Milestone #1 will be met."

A. Sanofi's Efforts With Respect to the Commercialization and Promotion of a Competitor Drug

91. Sanofi's promotion and commercialization of its competitor drug, Aubagio, for the treatment of multiple sclerosis, demonstrates that Sanofi failed to use efforts and employ the resources normally used by pharmaceutical companies to commercialize and promote Lemtrada.

92. Upon information and belief, Sanofi is not obligated to make any contingent payments to any entity as a result of the regulatory approval or sales of Aubagio similar to those contingent payments associated with sales of Lemtrada (*i.e.*, the Approval Milestone Payment, Product Sales Milestone payments (the "Milestone Payments"), and payments to Bayer under the LAPA).

93. In contrast to the inadequate efforts and resources Sanofi devoted to promoting and commercializing Lemtrada, Sanofi devoted significant efforts and resources into developing, promoting, and commercializing the competitor drug Aubagio.

94. In August 2011, Sanofi submitted a drug application to the FDA for approval to sell Aubagio for the treatment of relapsing multiple sclerosis, the same condition for which Lemtrada is indicated. Just over a year later, in September 2012, the FDA approved Aubagio.

95. Sanofi devoted substantially more efforts and resources to the hiring and training of the Aubagio sales team than to the Lemtrada sales team. In an interview with a pharmaceutical marketing news outlet, Carole Huntsman, Genzyme VP and Business Unit Head, acknowledged that "[i]n contrast with the Lemtrada staff, the Aubagio team came together 'really quickly' before the product's FDA approval." David Meeker, President and CEO of Genzyme, also stated on an investor earnings call on July 7, 2015, that "we put the [Lemtrada]

sales force fully in place only at the beginning of February", which was at least two months after FDA approval.

96. Sanofi and Genzyme conduct over 50% more consumer marketing events for Aubagio than they do for Lemtrada.

97. Sanofi and Genzyme provide more opportunities for patients who are taking Aubagio to share their experiences with other members of the multiple sclerosis community than Sanofi and Genzyme do for patients who have taken Lemtrada. Sanofi and Genzyme provide a website (https://www.aubagio.com/tell-your-story) in which patients who have taken Aubagio can offer to share their experiences with other members of the multiple sclerosis community and participate in Sanofi and Genzyme's "Ambassador" program. Sanofi and Genzyme do not provide a website inviting patients who have taken Lemtrada to share their experiences with other members of the multiple sclerosis community or participate in Sanofi and Genzyme's "Ambassador" program.

98. On a Sanofi- and Genzyme-sponsored website, Sanofi and Genzyme do not promote Lemtrada. Genzyme's website for Aubagio identifies nine different oral and injectable treatment options for patients with relapsing multiple sclerosis offered by different companies but does not identify Lemtrada as an available treatment option for patients with relapsing multiple sclerosis (https://www.aubagio.com/ms-medications).

99. Additionally, Sanofi and Genzyme provide more publicly available information about the necessary steps patients must take before beginning treatment with Aubagio than they do for patients who are preparing to begin treatment with Lemtrada (https://www.aubagio.com/starting-aubagio). Sanofi and Genzyme do not provide a website informing patients about the necessary steps patients must take before beginning treatment of

Lemtrada. This lack of information about Lemtrada makes it much less likely that doctors and patients will consider Lemtrada as a treatment option and eventually prescribe or receive the treatment.

100. In early 2013, approximately five months after approval of Aubagio, Sanofi touted the success of the Aubagio launch to its investors, reporting that over 80% of multiple sclerosis specialists in the U.S. had prescribed Aubagio and that Aubagio had a comparable growth trajectory in its initial weeks to the growth trajectory in the initial weeks of a previous blockbuster multiple sclerosis drug, Gilenya. By contrast, on a February 5, 2015 earnings call for Sanofi, nearly three months after approval of Lemtrada, Genzyme's CEO could only report that the Lemtrada team "just had our launch meeting here in the U.S." and only in the start of February was its sales force "fully deployed."

101. The following table compares the timeline of FDA approval and net sales for Aubagio and Lemtrada.

	AUBAGIO	**LEMTRADA**
FDA Application	August 2011	June 2012
FDA Approval	September 2012	November 2014
End-of-Year Net Sales	€7 million (2012)	€2 million (2013)
Year 1 Net Sales	€166 million (2013)	€34 million (2014)
Year 2 Net Sales	€443 million (2014)	€94 million (first-half 2015)

102. Had Sanofi and Genzyme used efforts and employed the resources normally used by companies in the pharmaceutical business to commercialize and promote Lemtrada, including but not limited to making appropriate expenditures to commercialize and promote Lemtrada, the Product Sales for Lemtrada would have been significantly higher, and

Product Sales Milestone #1 would have been met as early as the second quarter of 2015, and no later than the third quarter of 2015.

103. Sanofi's failure to meet Product Sales Milestone #1 by at least the third quarter of 2015 continues to adversely affect Sanofi's ability to meet each of the other Product Sales Milestones.

B. Sanofi Failed to Use Efforts and Employ Resources Normally Used by Pharmaceutical Companies to Launch Lemtrada in International Markets in a Timely Fashion

104. In February 2014, Genzyme President and CEO David Meeker announced that Sanofi "plans this year [2014] to launch Lemtrada in more than 30 countries, and hopefully additional markets where the treatment is still under review[.]" By the end of 2014, however, Sanofi had launched in only three of the six "Major Markets" identified in the CVR Agreement (the United States, the United Kingdom, France, Germany, Italy, and Spain) and fell dramatically short of its launch target.

105. Pursuant to the Diligent Efforts provision of the CVR Agreement, Sanofi undertook to "promptly seek[] pricing approvals and/or minimally restrictive payer coverage decisions in the Major Markets[.]" Sanofi's home market, France, is one of six Major Markets, but more than two years after Lemtrada was approved in the European Union and more than two years after the first commercial sale of Lemtrada in Germany, Sanofi has not sold a single dose of Lemtrada in France. In order for Product Sales in France to qualify in the calculation of Product Sales Milestone #1 (as a "Qualifying Major Market"), the first commercial sale in France must be made on or before December 31, 2015. Because of Sanofi's failure to use the required efforts to promote and commercialize Lemtrada, France has not become a Qualifying Major Market to date, which has adversely affected Sanofi's ability to meet Product Sales Milestones #1.

106. In contrast to the Lemtrada sales efforts, Sanofi's CEO Olivier Brandicourt boasted in an October 29, 2015 third-quarter earnings call that "Aubagio is now Genzyme's largest product by sales, driven by strong growth in the U.S., but also France[.]"

C. Sanofi Failed to Use Efforts and Employ Resources Normally Used by Pharmaceutical Companies to Develop and Commercialize Lemtrada in Light of the Known 2017 Patent Expiration

107. Diligent Efforts require Sanofi to use such efforts and employ such resources normally used by companies in the pharmaceutical business in the development and commercialization of Lemtrada, taking into account the launch or sales of a biosimilar product (which would include "generic" drugs).

108. U.S. Patent No. 6,120,766 (the "Lemtrada Patent") was issued on September 19, 2000. The Lemtrada Patent includes at least one claim that covers the use of Lemtrada as prescribed for multiple sclerosis.

109. No patent term extension is available for the Lemtrada Patent under applicable law. All other U.S. patents covering Lemtrada or its use will expire prior to September 19, 2017.

110. After September 19, 2017, Sanofi will not be able to prevent another company that obtains approval from the FDA and meets other statutory requirements from being able to sell a drug that is biosimilar to Lemtrada.

111. After expiration of the Lemtrada Patent, Sanofi will likely be forced to sell Lemtrada at a lower price and will generate less revenue from Lemtrada sales than they otherwise could have because generic manufacturers will be able to market and sell a drug that is biosimilar to Lemtrada after September 19, 2017.

112. Faced with the known expiration of the Lemtrada Patent, a company using normal efforts and resources in the pharmaceutical business would have sought to obtain

approval of Lemtrada in a manner that would maximize the period of time that Lemtrada could be sold under patent protection at a higher price. Sanofi did not maximize the commercialization potential of Lemtrada.

113. Sanofi's failure to devote the required efforts in light of the known expiration of the Lemtrada Patent adversely affected and continues to adversely affect Sanofi's ability to meet each of the Product Sales Milestones.

V. Sanofi Failed to Use Diligent Efforts in Achieving the Milestones Because it Took Into Account CVR Agreement Milestone Payments and Payments to Bayer in Evaluating the Profitability of Lemtrada

114. Sanofi failed to use Diligent Efforts because it took into account the Milestone Payments to the Trustee and the Bayer royalty payments when evaluating the profitability of Lemtrada.

115. Under the CVR Agreement, "Diligent Efforts" is defined as "such efforts and employing such resources normally used by Persons in the pharmaceutical business relating to the research, development or commercialization of a product" similar to Lemtrada, and taking into account certain issues including, but not limited to, Lemtrada's profitability. Under the same definition, Sanofi is not permitted to "treat royalty payments to [Bayer] as an expense. . . , or the achievement of Milestones in such a manner, that would reduce the profitability of the Product[.]" Sanofi did not use the required efforts because it took into account the Milestone Payments and obligations to Bayer in a manner that reduced profitability for Lemtrada.

116. In breach of the express provision of the CVR Agreement, Sanofi took into account the negative impact that these Milestone Payment obligations would have on its profitability in determining how to promote and commercialize Lemtrada. For example, had Sanofi met Product Sales Milestone #1 (*i.e.*, had Sanofi reached the required minimum of $400 million in sales during the contractually defined sales period), Sanofi would have been required

to make a $472 million payment to the Trustee, as trustee of an express trust for the benefit of the Holders, and another substantial payment to Bayer.

VI. Sanofi Breached the Implied Covenant of Good Faith and Fair Dealing

117. After issuing the CVRs to entice the Genzyme shareholders to agree to the acquisition by Sanofi, Sanofi engaged in conduct designed to keep Lemtrada sales volume low, delay the achievement of the Milestones, and depress the trading price of the CVRs, which, as of November 6, 2015, were trading at $0.10 per CVR.

118. Sanofi's delay in obtaining U.S. regulatory approval delayed sales of Lemtrada. In addition, Sanofi has kept the sales volume of Lemtrada low by failing to adequately promote and commercialize Lemtrada.

119. Sanofi has an incentive to engage in the foregoing conduct because of the Failure Purchase option. As explained *supra*, ¶¶ 32-33, the Failure Purchase option allows Sanofi to purchase all outstanding CVRs if the sales of Lemtrada and trading price of the shares (traded under the symbol "GCVRZ") remain below certain thresholds. By keeping sales volume low and failing to meet the Milestones, the GCVRZ trading price has been and continues to be depressed, which, in turn, maximizes Sanofi's opportunity to exercise the Failure Purchase option.

120. According to Sanofi's quarterly Product Sales statements for Lemtrada, aggregate gross product sales for the last four calendar quarters were only $127 million, well short of the pace needed to reach the $1 billion in sales in the four quarters preceding April 1, 2017 necessary to prevent Sanofi from exercising the Failure Purchase option.

121. Sanofi is further incentivized to depress the value and the trading price of the CVRs as Sanofi records an income when the value of the CVRs drops. Since the acquisition of Genzyme, Sanofi has recorded an income of €375 million as a direct result of the drop in the

market value of the CVRs. In the third quarter of 2015 alone, while the Holders suffered a 73% drop in the value of the CVRs, Sanofi reported an income of €109 million resulting from "a decrease in the fair value of contingent considerations related to the CVRs[.]"

122. The CVRs were an assurance to Genzyme's former shareholders that they would be adequately compensated in the Sanofi merger. By acting in bad faith to keep Lemtrada sales volume low, delay the achievement of the Milestones, and depress the trading price of the CVRs, Sanofi will have the ability to purchase and cancel all of the outstanding CVRs, thereby avoiding incurring any revenue-sharing costs associated with the Milestones, and extinguishing a large contingent liability on its balance sheet. Sanofi's actions have stripped, and will strip, the Trustee, on behalf of the Holders, of the benefit of its bargain—the right to receive payments within a defined period after the approval and meeting of sales thresholds of Lemtrada.

CAUSES OF ACTION

COUNT I
BREACH OF CONTRACT FOR FAILURE TO USE DILIGENT EFFORTS TO MEET THE APPROVAL MILESTONE

123. Plaintiff repeats and re-alleges the allegations of paragraphs 1 through 122 herein.

124. Section 7.10 of the CVR Agreement requires Sanofi to use Diligent Efforts, including causing its Affiliate, Genzyme, to take certain actions, to achieve the Approval Milestone for Lemtrada.

125. Sanofi failed to use Diligent Efforts to achieve the Approval Milestone by submitting or causing Genzyme to submit an inadequate Application for FDA approval of Lemtrada that failed to address the FDA's repeated concerns and requests for information regarding aspects of the Phase III trial design and results.

126. As a result of Sanofi's breach, the Approval Milestone was not met and Sanofi did not pay to the Trustee, for the benefit of the Holders, the Approval Milestone Payment. Therefore, the Trustee, as trustee of an express trust for the benefit of the Holders, has suffered damages.

COUNT II
BREACH OF CONTRACT FOR FAILURE TO USE DILIGENT EFFORTS TO MEET THE PRODUCT SALES MILESTONES

127. The Plaintiff repeats and re-alleges the allegations of paragraphs 1 through 122 herein.

128. Section 7.10 of the CVR Agreement requires Sanofi to use Diligent Efforts, including causing its Affiliate, Genzyme, to take certain actions, to achieve the Product Sales Milestones for Lemtrada.

129. Sanofi failed to use Diligent Efforts to meet Product Sales Milestone #1, thereby breaching the CVR Agreement by:

a. Failing to develop an appropriate REMS program and failing to seek to reduce the risk of side effects of Lemtrada. These failures led the FDA to limit Lemtrada's use to a third-line therapy, thereby harming the Holders' prospects for reaching the Product Sales Milestones;

b. Failing to use the efforts or employ the resources normally used by companies in the pharmaceutical business to operate timely and meaningfully in major markets; and

c. Treating the achievement of Milestones and the contingent payments to Bayer as an expense and a reduction in profitability for Lemtrada.

130. As a result of Sanofi's breach, the Product Sales Milestones have not been met and Sanofi has not paid to the Trustee, for the benefit of the Holders, any of the Product

Sales Milestone Payments. Therefore, the Trustee, as trustee of an express trust for the benefit of the Holders, has suffered damages.

COUNT III
BREACH OF THE IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING

131. The Plaintiff repeats and realleges the allegations of paragraphs 1 through 122 herein.

132. Sanofi breached the implied covenant of good faith and fair dealing in the CVR Agreement by delaying Lemtrada sales and keeping Lemtrada sales volume low, which has depressed the trading price of the CVRs.

133. Sanofi's actions or inaction have been taken in bad faith to maximize Sanofi's opportunity to exercise the Failure Purchase option, upon exercise of which, Sanofi will have the ability to purchase and cancel all of the outstanding CVRs, thereby avoiding incurring any revenue-sharing costs associated with the Milestones.

134. Sanofi's bad faith has stripped, and will strip, the Trustee, as trustee of an express trust for the benefit of the Holders, of the benefit of its bargain—the right to receive payments within a defined period after the approval and meeting of sales thresholds of Lemtrada.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court grant the following relief:

A. On Count I, a judgment that Sanofi breached its agreement with the Trustee with respect to the Approval Milestone and the Trustee, on behalf of the express trust for the benefit of the Holders, is entitled to an award of money damages in an amount to be determined at trial, but not less than $236,421,000;

B. On Count II, a judgment that Sanofi breached its agreement with the Trustee with respect to the Product Sales Milestones and the Trustee, on behalf of the express trust for the benefit of the Holders, is entitled to an award of money damages in an amount to be determined at trial;

C. On Count III, a judgment that Sanofi violated the covenant of good faith and fair dealing implied in its CVR Agreement with the Trustee and, therefore, the Trustee, on behalf of the express trust for the benefit of the Holders, is entitled to an injunction prohibiting Sanofi from exercising the Failure Purchase option and money damages in an amount to be determined at trial; and

D. Any such other and further relief as the Court may deem just, equitable, and proper.

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DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff demands trial by jury in this action of all issues so triable.

Dated: November 9, 2015
New York, NY

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